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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/845,154 | 05/01/2001 | Peter Bockstegers | 07883.0033 | 2668 |
| 22852 | 7590 | 10/22/2003 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005 | | | EXAMINER CHATTOPADHYAY, URMJ | |
| | | | ART UNIT 3738 | PAPER NUMBER |
| DATE MAILED: 10/22/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,154

Applicant(s)

BOEKSTEGERS, PETER

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 3,8,26,34-42,49,50 and 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-25,27-33,43-48,51-58,65 is/are rejected.
- 7) ☒ Claim(s) 62-64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 01 August 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 8/1/03 has been entered as Paper No. 8. The changes made to the specification, abstract, figures and claims have been approved by the examiner. Claims 66-88 have been canceled. During an updated search, the examiner came across a reference that can be used to reject applicant's claimed invention. Because this is a new art rejection, the following action is non-final.
2. In the non-final office action mailed 5/6/03, claims 49 and 50 were mistakenly considered for examination. These claims are drawn to the non-elected species of A.3, which is directed to a passageway-forming device that has two expandable mechanisms. Therefore, these claims are withdrawn from further consideration on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4-7, 9, 13, 14, 16-19, 23-25, 27-33, 46-48, 52-55, 57, 58 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Laroya et al. (USPAP 2002/0077566).

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Laroya et al. discloses a method of providing direct blood flow between a heart chamber and a coronary vessel with all the elements of claims 1 and 46. See Figure 7 for placing a guide device (120A) through an anterior wall and a posterior wall of the coronary vessel and through a heart wall between the heart chamber and the coronary vessel. See Figures 15A and 16A for forming a passageway in the heart wall at the location defined by the guide device by inserting and inflating balloon (178). See Figures 15A and 16A for placing and expanding a stent (172) within the passageway as it is being formed.

Claims 2, 4 and 5, see Figure 16A for the forming of the passageway including inflating the dilation mechanism (178).

Claims 6 and 47, see [0057] and Figure 13A for collapsible stent (172).

With respect to claims 7 and 9, see [0074] and [0075] for the forming of the passageway also including using a separate tissue removal device prior to inserting and inflating the dilation mechanism. This tissue removal device is disclosed by Rapacki et al. (USPAP 2002/0161424), which is incorporated by reference into the Laroya et al. reference. See [0094], lines 5-7 of Rapacki et al. for using the tissue removal device to facilitate easier placement of a conduit within the heart wall. Also see, [0097]-[0098] and [0101] of Rapacki et al. The tissue removal device shown in Figures 16A-16D of Rapacki et al. is the first mechanism for forming the passageway, and the delivery device (174 and 178) shown in Figure 13A of Laroya et al. is the second mechanism for placing the stent within the passageway after the first mechanism has been removed from the heart via the guide device (120A).

With respect to claims 13 and 14, see Figures 16A-16D, [0097] and [0101] of Rapacki et al. The first mechanism includes a stop mechanism (244) that engages an inner wall of the coronary vessel, and for expanding the stop mechanism (244).

Claims 16 and 52, see [0036] for guide device being a guidewire (120A).

Claims 17 and 53, see [0035] for inserting hollow needle (110) through anterior, posterior and heart walls prior to placing the guide device (120A).

Claims 18 and 54, see Figure 7 for inserting guidewire (120A) through hollow needle (110) until an end of the guidewire rests in the heart chamber.

Claims 19 and 55, see Figure 8 for removing the hollow needle (110) after inserting the guidewire (120A) therein.

Claims 23 and 57, see Figure 7 for avoiding intracardiac structures during insertion of the hollow needle.

Claims 24 and 25, see [0043], lines 8-11 and Figure 7 for placing the hollow needle and guide device therein at a predetermined angle.

Claims 27-29, 58 and 65, see Figures 15A and 16A for inflating balloon (178) carried by a catheter (174) over the guide device (120A) in forming the passageway and Figure 1 for deflating and removing balloon.

Claims 30-33 and 48, see Figures 14-16A for inflating the balloon (178) carried by a catheter (174) over the guide device (120A) to expand the stent (172).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 10-12 and 43-45 are rejected under 35 U.S.C. 103(a) as being obvious over Laroya et al. in view of Phelps et al. (USPN 6,290,728 as cited in applicant's IDS).

7. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

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8. Laroya et al. discloses a method of providing direct blood flow between a heart chamber and a coronary vessel with all the elements of claim 1, but is silent to the second mechanism including a stop mechanism at a substantial proximal end of the stent during stent delivery and the method further comprising advancing the stent within the passageway until the stop mechanism engages the posterior wall of the coronary vessel, as required by claims 10-12 and 43-45. Phelps et al. teaches implanting a stent within the heart wall to direct blood flow between a heart chamber and a coronary vessel, wherein a stent is advanced within the heart wall until a stop mechanism at a substantial proximal end of the stent engages the posterior wall of the coronary artery. See Figures 2-4 and column 6, lines 5-14 for the dumbbell shaped balloon (14) providing as the stop. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the balloon and stent of the second mechanism of Laroya et al. to the dumbbell balloon (14) and stent (10) of Phelps et al. in order for the balloon to flare out the ends of the stent, which maintain the stent in its proper position in the heart wall and provide a seal between the coronary vessel and the outer heart wall. The dumbbell balloon will also by nature of its shape, provide as a stop against the posterior wall of the coronary vessel, as shown in Figure 3.

9. Claims 15, 20-22, 51 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laroya et al. in view of Vanney et al. (USPN 6,029,672 as cited in applicant's IDS).

Laroya et al. discloses a method of providing direct blood flow between a heart chamber and a coronary vessel with all the elements of claim 1, but is silent to measuring the distance from the anterior wall of the coronary vessel to the left ventricle prior to placing the guide device

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and measuring the depth of insertion of the hollow needle by viewing markings thereon, as required by claims 15, 20-22, 51 and 56. Vanney et al. teaches measuring the thickness of the heart wall by observing external gradation marks on the guide needle in order to select an implant with a myocardial portion of sufficient length. See column 7, lines 42-56 and Figures 18-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Vanney et al. to have the hollow needle of Laroya et al. include markings in order to obtain the dimensions required to calculate the thickness of the heart wall and coronary vessel and all other required distances to select the proper size stent and catheter balloon.

Allowable Subject Matter

10. Claims 62-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

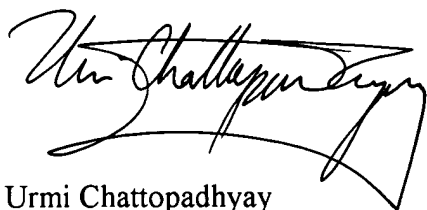
Response to Arguments

11. The statement of common ownership under M.P.E.P. 706.02(l)(2) filed 8/1/03 has overcome the 103(a) rejection of claims 1, 2, 4-7, 9-25, 27-33, 43-58 and 62-65 in the non-final office action mailed 5/6/03.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.


Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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October 10, 2003



David J. Isabella
Primary Examiner